



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

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~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

DP BARCODE No.: D429607; FILE SYMBOL No.: 2724-IUE (a); PRODUCT NAME: RF2236 CDSO-N1
for Dogs; DECISION No.: 506636; PC Code(s): 129032, 057001, 067501, 128965; ACTION CODE:
R301; FOOD Use: No

DATE OUT: October 22, 2015

SUBJECT: End Use Product Chemistry Review
Product Name: RF2236 CDSO-N1 for Dogs

FROM: Shyam Mathur, Ph.D
Product Chemistry Team Leader
CITAB/RD (7505P)

TO: Elizabeth Fertich / Jennifer Urbanski, RM 04
I-V Branch 1 / RD (7505P)

SB Mathur
10-22-15
PJ Urbanski
10/22/15

Company Name: Wellmark International
Formulation Type: Insecticide

INTRODUCTION:

The product chemistry data for the proposed product was reviewed previously (see PCR under DP428667; dated 08-25-2015). The Agency concluded that the proposed product is not identical to the cited product with Reg. No. 2596-168 and therefore, advised to submit the group B product chemistry and revise the CSF (if necessary) to support the registration of the proposed product. The group A data submitted earlier with MRID Nos. 49668001 & 49668002 were found to be acceptable. The registrant responded on October 2, 2015 and submitted group B product chemistry data with MRID No. 49737901 and the revised basic CSF dated 09-23-2015. CITAB has been asked to review the submitted group B product chemistry data and the proposed revised basic CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Etofenprox (55.0%), PBO (10.0%), MGK-264 (1.0%) and NyLar (0.50%)
2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes, give the registration number of the cited product.

Reg. No. 2596-168

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3. All of the source materials of the active ingredient are derived from registered sources: ☒ Yes ☐ No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: ☒ Yes; ☐ No

5. Confidential Statement of Formula(s):

☒ Proposed Basic - Dated: 07-02-2015; Re-submitted – Dated: 09-23-2015

☐ Proposed Alternate CSF – All Dated: ; Re-submitted – All Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA;

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?
☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		N	49668002
830.1600	Description of materials used to produce the product		X		A	49668002
830.1650	Description of formulation process		X		A	49668002
830.1670	Discussion on the formation of impurities		X		A	49668002
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		N	Basic CSF dated 07-02-2015
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		cited		A	49668001

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B: Submitted under self-certification dated 09-23-2015

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos. cited
830.6303	Physical State	Liquid @ 22.8°C	A	49737901
830.6314	Oxidation/reduction	Does not contain any oxidizing or reducing agents	A	49737901
830.6315	Flammability	179.96 °F (355.95 °F)	A	49737901
830.6316	Explosibility	Not potentially explosive	A	49737901
830.6317	Storage stability	Study in progress	I	49737901
830.6320	Corrosion characteristics	Study in progress	I	49737901
830.7000	pH	Not dispersible in water non-aqueous product)	A	49737901
830.7100	Viscosity	44.79 cps @ 20°C 16.88 cps @ 40°C	A	49737901
830.7300	Density	8.54 lbs/gal (1.0242 g/ml) @20.0°C	A	49737901

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CONCLUSIONS:

The CITAB has reviewed the group B product chemistry data and the revised basic CSF submitted for the proposed end-use product and has concluded that:

1. The proposed revised basic CSF (dated 09-23-2015) submitted is acceptable.
2. The product chemistry data submitted (self-certification, 09-23-2015) corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explosibility), 830.7000 (pH), 830.7100 (viscosity) and 830.7300 (density) are acceptable.
3. The registrant has stated that the studies corresponding to the guidelines 830.6317 (storage stability), 830.6320 (corrosion characteristics) are in progress. The registrant must submit the results of these study to the Agency for evaluation.
4. The data submitted corresponding to guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce product), 830.1650 (description of formulation process), 830.1670 (description of formation of impurities), and 830.1750 (certified limits) and cited data for 830.1800 (enforcement analytical method) have been found to be acceptable earlier by the Agency.